OCT 16 2003

K033099

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Applied Diabetes Research, Inc.
1740 South IH 35E, Suite 112
Carrollton, TX 75006

Phone Number: 972-446-9396
Fax Number: 972-446-9397
Contact: Rick Lynch
President
Date: September 26, 2003

B. Device Information

Trade/Proprietary Name: ADR THINSet Insulin Infusion Set

Common name of device: Infusion Set

Classification Name: Set, Administration, Intravascular

C: Predicate Device: ADR SmartSet Insulin Infusion Set

Predicate 510(k) #: K012429

D. Device Description:

The ADR THINSet Insulin Infusion Set facilitates the flow of medication from an infusion pump reservoir into the subcutaneous tissue of the user. The infusion set consists of a female luer, tubing, Needle Grip with introducer needle and Base Assembly. The Base Assembly consists of three components: the Needle Grip, Connector and Base. The Needle Grip contains the 26 guage introducer needle that penetrates the subcutaneous tissue. The infusion set tubing attaches to the Connector. The Connector may be removed from the Base. The Base houses the 24 gauge Cannual and has a medical grade adhesive dressing attached to the bottom.

The infusion set is packaged sterile in a Tray Pack. The infusion set is available with 23 and 43 inch tubing lines and 6 and 9 mm Cannulas.

E. Intended Use:

The ADR THINSet Infusion Set is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The set is not intended nor indicated for use with blood or blood products.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the ADR THINSet Insulin Infusion Set and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

Prior to testing, First Article Inspections were conducted on all components. In addition, material verification was performed on all components.

The ADR THINSet Insulin Infusion set was tested per the requirements of the ISO-FDA Modified Matrix, FDA/ODE General Program Memorandum - # G95-1 and ANSI/AAMI/ISO 10993-1:1997 for a External communicating device, Blood path, indirect for a period less than 30 days.

Biocompatibility testing included Cytotoxicity, Intracutaneous Reactivity, Maximization Sensitization Study, In Vitro Hemolysis Study, USP and ISO Systemic Toxicity Studies and USP Prorogen Study. In addition, insulin compatibility testing was performed.

The distal end of the infusion set has a standard Female Luer lock. As part of the performance testing, the Female Luer lock shall meet the requirements of the Gauging, Leakage, Separation force, Unscrewing torque, Ease of assembly, Resistance to overriding, Stress cracking tests detailed in ISO 594-2, Conical fittings with 6% (Luer) taper for reservoirs, needles and certain other medical equipment – Part 2: Lock fittings.

The accuracy of the flow rates through the ADR THINSet Insulin Infusion Set was verified by dose accuracy testing.

The intended use of the ADR THINSet Insulin Infusion Set is identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Conclusion:

The ADR THINSet Insulin Infusion Set is substantially equivalent to the ADR SmartSet Insulin Infusion Set in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Applied Diabetes Research, Incorporated
C/O Mr. Jim Barley
JB & Associates
28481 La Falda
Laguna Niguel, California 92677

Re: K033099
Trade/Device Name: THINSet Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Setg
Regulatory Class: II
Product Code: FPA
Dated: September 26, 2003
Received: September 29, 2003

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

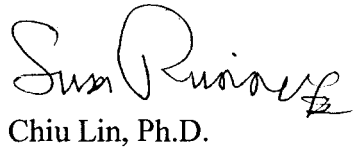
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033099

Device Name: THINSet Infusion Set

Indications for Use:

The ADR THINSet Infusion Set is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The set is not intended nor indicated for use with blood or blood products.

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033099

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)